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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CELSA, BENNETT M

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/057,940	Applicant(s) PANTOLIANO ET AL.	
	Examiner Bennett Celsa	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-70 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 31-70 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of the Claims

Claims 1-30 have been cancelled.

Claims 31-70 are currently pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 31-32 and 36-47, drawn to a 1st method of determining biological protein function, classified in class 436, subclass 501.
- II. Claims 33-34 and 48-59, drawn to a 2nd method of determining biological protein function, classified in class 435, subclass 7.1***
- III. Claims 35 and 60, drawn to a 3rd method of determining biological protein function, classified in class 530, subclass 350+.
- IV. Claims 61-69 (in part), drawn to a vitamin probe library, classified in class 426, subclass 72.
- V. Claims 61-69 (in part), drawn to a coenzyme probe library, classified in class 424, subclass 94.1.
- VI. Claims 61-69 (in part), drawn to an amino acid residue function (and mimics thereof) group probe library, classified in class 564, subclass 230.
- VII. Claims 61-69 (in part), drawn to metal chelator probe library, classified in class 546, subclass 156.
- VIII. Claims 61-69 (in part), drawn to metal ion probe library, classified in class
***, subclass ***.

Art Unit: 1639

- IX. Claims 61-69 (in part), drawn to a carbohydrate library, classified in class 536, subclass 23.1.
- X. Claims 61-69 (in part), drawn to nucleic acid library, classified in class 536, subclass 28.5.
- XI. Claims 61-69 (in part), drawn to lipid library, classified in class 554, subclass 227.
- XII. Claims 61-69 (in part), drawn to an enzyme library, classified in class 435, subclass 213.
- XIII. Claims 61-69 (in part), drawn to steroid library, classified in class 552, subclass 530.
- XIV. Claims 61-69 (in part), drawn to an amine hormone library, classified in class 514, subclass 11.
- XV. Claims 61-69 (in part), drawn to an alkaloid library, classified in class 514, subclass 283.
- XVI. Claims 61-69 (in part), drawn to "generic drug molecule" library, classifiable according to "drug".
- XVII. Claims 61-69 (in part), drawn to "natural product" library, classifiable according to "natural product".
- XVIII. Claim 70, drawn to an apparatus, classified in class 422, subclass 102; class 435, subclasses 82.08 and 808.

Art Unit: 1639

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are drawn to independent and/or patentably distinct methods due to these methods encompassing different method steps, method reagents and modes of operation; require different and separately burdensome manual/computer searches in patent and literature databases; and require different examination burdens raising different issues under 35 USC 112, 102 and 103, wherein art applicable to one group may not be applicable to another e.g. will not anticipate and/or render obvious.

Inventions IV-XVII are drawn to independent and/or patentably distinct product libraries, since the individual products (e.g. peptides, saccharides, lipids etc.) composing the individual libraries are drawn to compounds which are structurally distinct, possess different biological/physical/chemical properties are capable of separate manufacture and/or use; possess different core structure required for a common utility; require different and separately burdensome manual/computer searches in patent and literature databases; and require different examination burdens raising different issues under 35 USC 112, 102 and 103, wherein art applicable to one group may not be applicable to another e.g. will not anticipate and/or render obvious.

Invention XVIII drawn to apparatus is independent and/or patentably distinct from the methods of Inventions I-III as well as the product libraries of Inventions IV-XVII since the apparatus is directed to a different statutory class of invention; the apparatus is not especially adapted for use in the methods of Inventions I-III nor do the methods of Inventions I-III necessarily require the use of the apparatus; the product libraries do not necessarily require the use of the apparatus for purposes of screening, nor is screening

Art Unit: 1639

of the library compounds restricted to the use only of the claimed apparatus; the apparatus requires different and separately burdensome manual/computer searches in patent and literature databases as compared to the method or library claims since the apparatus possesses components not present in the method or library claims; and the apparatus requires different examination burdens raising different issues under 35 USC 112, 102 and 103, wherein art applicable to one group may not be applicable to another e.g. will not anticipate and/or render obvious.

Because these inventions are distinct for the reasons given above: and

- a. have acquired a separate status in the art as shown by their different classification; and/or
- b. require different and separately burdensome manual/computer bibliographic searches; and/or
- c. because these inventions possess recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species (For Groups I-III)

The independent method claims of Groups I-III are generic to the classification of a plurality of disclosed patentably distinct species of "target proteins" including (but not limited to) thrombin, trypsin, plasmin, Factor Xa, recombinant dimeric lac repressor etc. which individual methods require different and separately burdensome manual/computer searches in patent and literature databases; and require different examination burdens raising different issues under 35 USC 112, 102 and 103, wherein

Art Unit: 1639

art applicable to one group may not be applicable to another e.g. will not anticipate and/or render obvious.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (e.g. a single target protein to be classified such as trypsin), even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election of Species (For Group IV- XVIII)

This application contains claims directed to the following patentably distinct species of the claimed invention: apparatus containing libraries comprising:

- a. vitamins (e.g. biotin etc.) ;
- b. coenzymes (e.g. ATP/ADP etc.) ;
- c. amino acid residues (e.g. guanidino etc.) ;
- d. metal chelators (e.g. EDTA etc.);
- e. metal ions (e.g. calcium etc.);
- f. carbohydrates (e.g. glucose, xylose etc.) ;
- g. nucleic acids (e.g. uracil, guanidine, DNA etc.);
- h. lipids (e.g.

Art Unit: 1639

i. enzymes (e.g.

j. steroids (e.g.

k. amine hormones

l. alkaloids

m. "generic drug molecules"

n. "natural products"

each drawn to independent and/or patentably distinct product

libraries, since the individual products (e.g. peptides, saccharides, lipids etc.)

composing the individual libraries are drawn to compounds which are structurally

distinct, possess different biological/physical/chemical properties are capable of

separate manufacture and/or use; possess different core structure required for a

common utility; require different and separately burdensome manual/computer searches

in patent and literature databases; and require different examination burdens raising

different issues under 35 USC 112, 102 and 103, wherein art applicable to one group

may not be applicable to another e.g. will not anticipate and/or render obvious.

Applicant is required under 35 U.S.C. 121 to elect BOTH

1. a single disclosed species class (e.g. from a-n above):

2. a single compound which is representative of the species class (e.g.

vitamins and vitamin E).

for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Art Unit: 1639

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-273-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BC
June 9, 2004

Bennett Celsa
Primary Examiner
Art Unit 1639

